4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0354]

Acrotech Biopharma LLC; Withdrawal of Approval of New Drug Application for MARQIBO (VinCRIStine Sulfate LIPOSOME Injection), 5 milligrams/5 milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 milligrams (mg)/5 milliliters (mL), held by Acrotech Biopharma LLC (Acrotech), 29 Princeton Hightstown Rd., East Windsor, NJ 08520. Acrotech has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On August 9, 2012, FDA approved NDA 202497 for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5 mL, for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of MARQIBO (vinCRIStine sulfate LIPOSOME injection) for Ph-ALL included a required postmarketing clinical trial intended to verify the clinical benefit of MARQIBO (vinCRIStine sulfate LIPOSOME injection).

On September 24, 2021, FDA published the *Federal Register* notice "Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments," announcing that MARQIBO (vinCRIStine sulfate LIPOSOME injection) would be discussed at an Oncologic Drug Advisory Committee Meeting (ODAC) scheduled for December 2, 2021 (86 FR 53067). On October 27, 2021, FDA met with Acrotech to discuss the planned ODAC meeting. At that meeting, the Agency recommended the applicant voluntarily request withdrawal of approval for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5mL, due to the lack of verification of clinical benefit. The postmarketing trial required to verify clinical benefit had not been completed, and patient recruitment to fulfill the PMR appeared to be significantly challenging due to the treatment options that are currently available.

On November 19, 2021, Acrotech submitted a letter asking FDA to withdraw approval of NDA 202497 for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5mL, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing. On November 23, 2021, FDA acknowledged Acrotech's request for withdrawal of approval of the NDA and waiver of its opportunity for hearing. FDA also cancelled the ODAC meeting scheduled for December 2, 2021, since Acrotech's withdrawal request made discussion at an advisory committee meeting moot.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 202497 for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5mL, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of MARQIBO (vinCRIStine sulfate LIPOSOME injection) 5 mg/5mL, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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